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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/117,838	08/12/1998	OLEG LLIICH EPHSTEIN		4128

7590

06/06/2006

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EXAMINER
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PESELEV, ELLI

ART UNIT	PAPER NUMBER
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1623

DATE MAILED: 06/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/117,838	EPHSTEIN, OLEG LLIICH	
	<b>Examiner</b>	<b>Art Unit</b>	
	Elli Peseelev	1623	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 23 January 2006 and 23 May 2006.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 17, 19-23 and 25-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 17, 19-23 and 25-37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

The numbering of claims is not in accordance with 37 CFR 1.126 which requires the original numbering of the claims to be preserved throughout the prosecution. When claims are canceled, the remaining claims must not be renumbered. When new claims are presented, they must be numbered consecutively beginning with the number next following the highest numbered claims previously presented (whether entered or not).

Misnumbered claims 36-38 have been renumbered 35-37.

Claims 19-21, 25 and 26 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement for the reasons set forth in the Office Action of July 14, 2005.

Claims 17, 19-23 and 25-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is not clear what is meant by the terminology "making from an initial material an active medicinal substance" (claim 17). From what initial material? Does it involve chemical reactions or making of a pharmaceutical composition? It is not clear from claim 17 how a potentiated medicinal substance is produced by a homeopathic method from an initial material. It is not clear what is meant by the term "potentiated" (all occurrences). Also, it is not clear how the medicinal substance is produced.

There is no antecedent basis in claim 17 for the terminology "said combining" in claims 19-22. It is not clear what is encompassed by the term "impregnating" (claims 19 and 25). Does it mean the two substances are some how attached and if so how?

In claims 23-34, it is not clear how an active medicinal substance differs from a potentiated medicinal substance since both substances are produced from the same initial material.

The terms "Atropini Sulfati C30" (claim 29), "aciolum salicylicum" (claim 30), "prednizolon Prednizolon in 1200 dissolving) Cortex, C12" (claim 31), "Insulinum C30" (claim 32), "Zincum Metallicum" (claim 33) and "Sarcolysinum 200" (claim 34) are not art recognized terms.

The method claims 35-37 are indefinite in that it is not clear what is being treated.

Claims 35 and 36 are substantial duplicates.

It is not clear how two substances combined with one another can be introduced separately into the organism as defined by claim 37.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 17, 19-23 and 25-28 and 36-37 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,324).

Jonsson et al disclose a method of making a pharmaceutical composition by combining one or more active substances and a method of treatment with said composition. Since, the active substance and a homeopathic substance encompassed by the present claims are seen to be the same substance in different concentrations, the claimed methods and compositions are encompassed by the reference's methods and compositions. In addition, if there are any differences between the claimed methods and compositions and the prior art's methods and compositions, the differences would appear to be minor in nature and the claimed methods and compositions, which fall within the scope of the prior art's methods and compositions, would have been prima facie obvious from the said reference's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.

Claim 29 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Cohen et al (U.S. Patent No. 3,901,967).

Claim 29 is directed to a medicine comprising as the active substance a therapeutic dose of atropine sulfate and Aproini Sulfate C30 produced by consecutive dissolving and shaking of the atropine. Cohen et al disclose a pharmaceutical composition comprising atropine sulfate. Since dissolving and shaking atropine produces nothing more than atropine, the claimed composition reads on nothing more

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than a pharmaceutical composition comprising atropine sulfate disclosed by Cohen et al. In addition, if there are any differences between the claimed composition and the prior art composition, the differences would appear to be minor in nature and the claimed composition, which falls within the scope of the prior art's composition, would have been prima facie obvious from the said prior art's disclosure, to a person having ordinary skill in the art at the time the claimed invention was made.

Claim 30 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Sirany (U.S. Patent No. 4,987,127).

Claim 30 is directed to a medicine comprising as an active substance acetylsalicylic acid and acidum salicylicum obtained by impregnation of milk sugar with a solution of acidum salicylicum. Sirany discloses a pharmaceutical composition comprising acetylsalicylic acid. Since acidum salicylicum is not seen to be structurally different from acetylsalicylic acid, the claimed composition reads on the composition disclosed by Sirany. In addition, if there are any differences between the claimed composition and the prior art composition, the differences would appear to be minor in nature and the claimed composition, which falls within the scope of the prior art's composition, would have been prima facie obvious from the said reference's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.

Claim 31 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Nobile (U.S. Patent No. 3,134,718).

Claimed 31 is directed to a medicine comprising as an active substance Prednizolon and Prednizolon produced by dilution of Prednizolon. Nobile discloses a

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pharmaceutical composition comprising Prednizolon. Since dilution of Prednizolon produces nothing more than Prednizolon, the claimed composition reads on the prior art's composition. In addition, if there are any differences between the claimed composition and the prior art's composition, the differences would appear to be minor in nature and the claimed composition, which falls within the scope of the prior art's disclosure, would have been prima facie obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.

Claim 32 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Massey et al (U.S. Patent No. 4,839,341).

Claim 32 is directed to a medicine comprising as an active substance insulin insulinum C30 which is produced by a homeopathic method from insulin. Massey et al disclose a pharmaceutical composition comprising insulin. Since insulinum C30 is not seen to be structurally different from insulin, the claimed composition reads on the prior art's composition. In addition, if there are any differences between the claimed composition and the prior art's composition, the differences would appear to be minor in nature and the claimed composition, which falls within the scope of the prior art's composition, would have been prima facie obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.

Claim 33 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Jonsson et al (U.S. Patent No. 4,292,324).

Claim 33 is directed to a medicine comprising as an active substance paste from zinc and Zincum Metallicum produced from zinc. Jonsson et al disclose a pharmaceutical composition comprising zinc. Since Zincum Metallicum is not seen to be different from zinc, the claimed composition reads on the prior art's composition. In addition, if there are any differences between the claimed composition and the prior art's composition, the differences would appear to be minor in nature and the claimed composition, which falls within the scope of the prior art's composition, would have been prima facie obvious from the said reference's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.

Claim 34 is rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Albert Stock John et al (U.S. Patent No. 3,032,584).

Claim 34 is directed to a medicine comprising as an active substance Sarcolysin and Sarcolysinum 200 produced from Sarcolysin. Albert Stock John et al disclose a pharmaceutical composition comprising Sarcolysin. Since Sarcolysinum 200 is not seen to be structurally different from Sarcolysin, the claimed composition reads on the prior art's composition. In addition, if there are any differences between the claimed composition and the prior art's composition, the differences would appear to be minor in nature and the claimed composition, which falls within the scope of the prior art's composition, would have been prima facie obvious from the said prior art's disclosure to a person having ordinary skill in the art at the time the claimed invention was made.



Applicant's arguments filed January 23, 2006 and May 23, 2006 have been fully considered but they are not persuasive.

Applicant contends that potentiating substance is not the same as the active substance. However, the applicant has failed to explain how the two substances differ structurally. It seems that a potentiating substance is produced by dilution of the active substance so that when the two substances are combined there is no difference between a composition comprising an active substance and a composition comprising an active substance and a potentiating substance.

The Declarations by Evgeniy D. Goldberg, Tatyana A. Voronina, Oleg Epstein have been considered but have not been found persuasive because said declarations fail to explain how a combination of the active substance and a homeopathic substance produced from the same initial material is different from the composition comprising an active substance since homeopathic substance is nothing more than a diluted version of the active substance. Further, the declarations fail to provide any data showing the advantages produced by combining an active substance with a homeopathic substance.

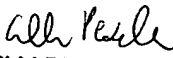
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elli Peselev whose telephone number is (571) 272-0659. The examiner can normally be reached on 8.00-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia Jiang can be reached on (571) 272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Elli Peselev

  
**ELLI PESELEV**  
**PRIMARY EXAMINER**  
**GROUP 1200**